IBUPROFEN- ibuprofen capsules 200 mg capsule, liquid filled TIME CAP LABORATORIES, INC.

610T Timely 49483-133 Ibuprofen Capsules 200 mg

DRUG FACTS

Active ingredient (in each capsule)

Solubilized Ibuprofen equal to 200 mg ibuprofen (NSAID)* (present as the free acid and potassium salt) * nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

• temporarily relieves minor aches and pains due to :

headache toothache backache menstrual cramps the common cold muscular aches minor pain of arthritis

temporarily reduces fever

Warnings

Allergy alerts: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains an NSAID, which may cause

severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

• take with food or milk if stomach upset occurs

Stop use and ask a doctor if

• you experience any of the following signs of stomach bleeding:

feel faint vomit blood have bloody or black stools have stomach pain that does not get better

• you have symptoms of heart problems or stroke:

chest pain trouble breathing weakness in one part or side of body slurred speech leg swelling

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a

Poison Control Center right away (1-800-222-1222).

Directions

do not take more than directed

the smallest effective dose should be use

adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist

- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor

children under 12 years: ask a doctor

OTHER INFORMATION

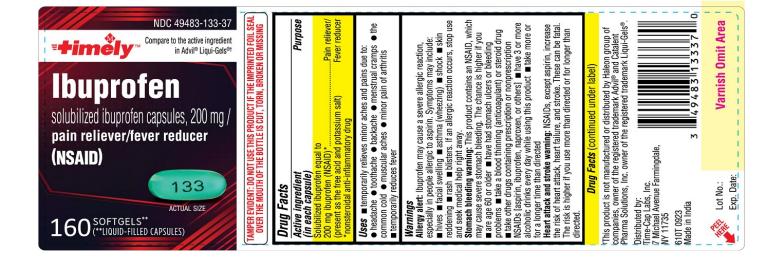
Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use
- store at 20-25°C(68-77 °F)
- avoid excessive heat above 40°C(104 °F)

Inactive ingredients Ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, propylene glycol, potassium hydroxide, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

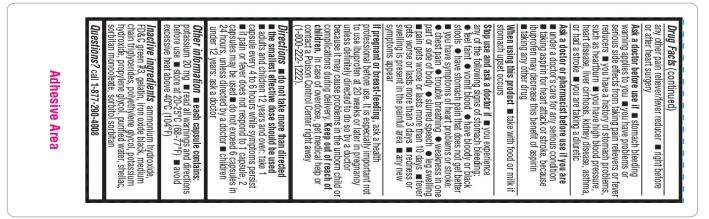
Questions or comments? call 1-877-290-4008

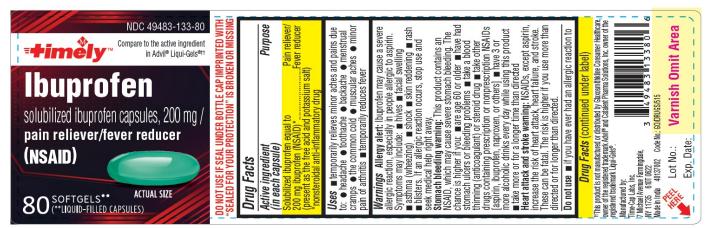
Adhesive Area	Other information ■ each capsule contains: potassium 20 mg ■ read all warnings and directions ■ store at 20-25°C (68-77°F) ■ avoid excessive hear (104°F) Inactive ingredients ammonium hydroxide, FDS gelatin, iron oxide black, medium chain trigbycerides, polyethylene glycol, potassium hydroxide, propylene purified water, shellac, sorbitan monooleate, sorbiton Questions or comments? Call 1-877-290-4008	In pregnant or preast-recting, ask a nearin protessional before use. It is especially important not to use bluprofen at 20 weeks co later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. (1-800-222-1222). <i>Directions</i> ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 capsule. 2 capsules may be used ■ do not exceed 6 capsules in 24 hours, doctor	nt int int int int int int int int int i	uretid
2	• contains: excessive heat above 40°C vydroxide, FD&C green #3, 1 triglycerides, 1 triglyc	sik a nearin proressional berore not to use ibuprofen at 20 weeks or itely directed to do so by a doctor s in the unborn child or In case of overdose, get medical ol Center right away e dults and children 12 years 4 to 6 hours while symptoms not respond to 1 capsule, 2 t exceed 6 capsules in 24 hours, children under 12 years: ask a	ing signs of stomach bleeding: re bloody or black stools ot get better ● weakness in one part or side swelling an 10 days han 3 days n the painful area	d an allergic reaction to any mach bleeding warning applies serious side effects from taking you have a history of stomach ney disease, asthma, or had a c re use if you are under a dition taking aspirin for heart dition taking aspirin for heart en may decrease this benefit of with food or milk if stomach



<i>Questions?</i> call 1-877-290-4008	Other information = each capsule contains: potassium 20 mg = read all warnings and directions before use store at 20-25 °C (68-77 °F) = avoid excessive heat above 40°C (104°F) Inactive ingredients anmonium hydroxide, FD&C green no. 3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan	Directions = do not take more than directed = the smallest effective dose should be used = adults and children 12 years and over take t capsule every 4 to 6 hours while symptoms persist = if pain or fever does not respond to 1 capsule, 2 capsules may be used = do not exceed 6 capsules in 24 hours, unless directed by a doctor = children under 12 years: ask a doctor	Stop use and ask a doctor if wou experience any of the following signs of stomach bleeding: • feel faint • vomit blood • have bloody or black stolds • have stamach plain that does not get better would be breathing • weakness in one part or side of body • slurred speech • leg swelling worse or lasts more than 10 days weakness in a process or swelling is present in the painful area wany new symptoms appear I regulated the symptoms appear I regulated to do sy weakness to work a doctor breause it may cause problems in the unborn child or complications during delivery. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).	Ask a doctor hebore use if a stomach bleeding warning applies to you aryou have problems or serious side effects from taking pain relievers or fever reducers a you have a history of stomach problems, such as heartburn avou have high blood or had a stroke aryou are taking a diuretic Ask a doctor or pharmackic hefore use if you are a under a doctor's care for any serious condition a taking aspirin for reart attack or stoke, because luburroten any decrease this benefit of aspirin a taking any other drug When using this product a take with food or milk if stomach used occurs	<i>Drug Facts</i> (continued) Do not use ■ If you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery
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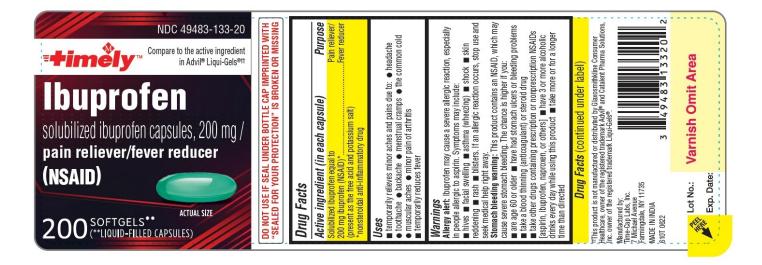


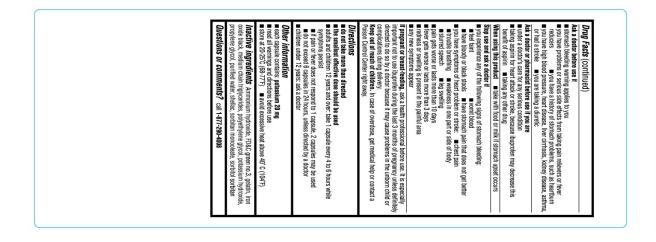
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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 capsule, 2 capsules may be used ■ do not exceed 6 capsules in 24 hours, unless directed ■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F) Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, 107 11735 1610T 0622 Made in India by a doctor **■** children under 12 years: *ask a doctor Other information ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause . attack, heart failure, and stroke. These -can be fatal. The risk is higher if you use more than directed or for longer than ■ do not take more than directed ■ the smallest effective dose should be used problems in the unborn child or If pregnant or breast-feeding, ask a nealth professional before use. It is especially important not to use adults and children 12 years and over directed. Directions **Questions?** call **1-877-290-4008** Distributed by: Adhesive Area

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(NSAID) 20 SOFTGELS** (**LIQUID-FILLED CAPSULES)	The Constitution of the second second and the second part of the warkings The warkings The second se	Lot No.: Exp Date:



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IBUPROFEN					
ibuprofen capsules 200 mg ca	apsule, liquid filled				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49	483-133
Route of Administration	ORAL				
Active Ingradient/Active	Majaty				
Active Ingredient/Active	Molecy				
Ingred	lient Name		Basis of Stre	ngth	Strength
IBUPROFEN (UNII: WK2XYI10QM) (I	BUPROFEN - UNII:WK2XYI10	QM)	IBUPROFEN		200 mg

Ingredient Name FER (UNII: 059QF0K00R) LLAC (UNII: 46N107B710) C GREEN NO. 3 (UNII: 3P30NR601S) MONIA (UNII: 5138Q19F1X) ATIN (UNII: 2G86QN327L) ROSOFERRIC OXIDE (UNII: XM0M87F357) YETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MQ0SDW1A)	Strength
LLAC (UNII: 46N107B710) C GREEN NO. 3 (UNII: 3P30NR6015) MONIA (UNII: 5138Q19F1X) ATIN (UNII: 2G86QN327L) ROSOFERRIC OXIDE (UNII: XM0M87F357)	
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ATIN (UNII: 2G86QN327L) ROSOFERRIC OXIDE (UNII: XM0M87F357)	
ROSOFERRIC OXIDE (UNII: XM0M87F357)	
YETHYLENE GLYCOL, UNSPECIFIED (UNII: 3W00SDW1A)	
DIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PYLENE GLYCOL (UNII: 6DC9Q167V3)	
ASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
BITAN MONOOLEATE (UNII: 06XEA2VD56)	
BITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	133
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-133- 31	300 in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2021	
2	NDC:49483-133- 23	1 in 1 CARTON	06/16/2022	
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49483-133- 80	80 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2022	
4	NDC:49483-133- 12	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2022	
5	NDC:49483-133- 20	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2022	
6	NDC:49483-133- 37	160 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2023	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA079205	07/27/2021				

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-133)

Revised: 9/2023

TIME CAP LABORATORIES, INC.